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Risk Assessment
Guidance for Superfund
Volume I
Human Health Evaluation Manual
(Part A)

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chemical in a medium is first scored according to its concentration and toxicity to obtain a risk factor (see the box below). Separate scores are calculated for each medium being evaluated.

The units for the risk factor R_{ij} depend on the medium being screened. In general, the absolute units do not matter, as long as units among chemicals in a medium are the same. To be conservative, the concentration used in the above equation should be the maximum detected concentration determined according to procedures discussed in Chapter 6, and toxicity values should be obtained in accordance with the procedures discussed in Chapter 7.

Chemicals without toxicity values cannot be screened using this procedure. Such chemicals should always be discussed in the risk assessment as chemicals of potential concern; they should not be eliminated from the risk assessment. Guidance concerning chemicals without toxicity values is provided in Chapter 7.

For some chemicals, both oral and inhalation toxicity values are available. In these cases, the more conservative toxicity values (i.e., ones yielding the larger risk factor when used in the above equation) usually should be used. If only one exposure route is likely for the medium being evaluated, then the toxicity values corresponding to that exposure route should be used.

Calculate total chemical scores (per medium). Chemical-specific risk factors are summed to obtain the total risk factor for all chemicals of potential concern in a medium (see the box on this page). A separate R_j will be calculated for carcinogenic and noncarcinogenic effects. The ratio of the risk factor for each chemical to the total risk factor (i.e., R_{ij}/R_j) approximates the relative risk for each chemical in medium j.

Eliminate chemicals. After carefully considering the factors discussed previously in this subsection, eliminate from the risk assessment chemicals with R_{ij}/R_j ratios that are very low compared with the ratios of other chemicals in the medium. The RPM may wish to specify a limit for this ratio (e.g., 0.01; a lower fraction would be needed if site risks are expected to be high). A chemical that contributes less than the specified fraction of the total risk factor for each medium would not be considered further in the risk assessment for that medium. Chemicals exceeding the limit would be considered likely to contribute significantly to risks, as calculated in subsequent stages of the risk assessment. This screening procedure could greatly reduce the number of chemicals carried through a risk assessment, because in many cases only a few chemicals contribute significantly to the total risk for a particular medium.

TOTAL CHEMICAL SCORES

$$R = R_{1j} + R_{2j} + R_{3j} + \ldots + R_{ij}$$

where

Rj = total risk factor for medium j; and

$R_{1j} + \ldots + R_{ij}$ = risk factors for chemicals 1 through i in medium j.

The risk factors developed in this screening procedure are to be used only for potential reduction of the number of chemicals carried through the risk assessment and have no meaning outside of the context of the screening procedure. They should not be considered as a quantitative measure of a chemical's toxicity or risk or as a substitute for the risk assessment procedures discussed in Chapters 6, 7, and 8 of this guidance.

5.10 SUMMARY AND PRESENTATION OF DATA

The section of the risk assessment report summarizing the results of the data collection and evaluation should be titled "Identification of Chemicals of Potential Concern" (see Chapter 9). Information in this section should be presented in ways that readily support the calculation of exposure concentrations in the exposure assessment portion of the risk assessment. Exhibits 5-6 and 5-7 present examples of tables to be included in this section of the risk assessment report.

Comment [A23]: EPA's Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part D, Standardized Planning, Reporting, and Review of Superfund Risk Assessments) provides planning tables for use during the risk assessment process, including the data evaluation stages. *See* Part D, Section 3.1.1 (page 3-4) for an overview of using Planning Table 2: Occurrence, Distribution, and Selection of COPCs. Also see Appendix A for the downloadable Planning Table 2 template and instructions for completing Table 2. RAGS, Part D may be found at: http://www.epa.gov/oswer/riskassessment/ragsd/index.htm.

Definition of the physical setting. The initial characterization of the physical setting that defines the risk assessment for a Superfund site involves many professional judgments and assumptions. These include definition of the current and future land uses, identification of possible exposure pathways now and in the future, and selection of substances detected at the site to include in the quantitative risk assessment. In Superfund risk assessments, particular attention should be given to the following aspects of the definition of the physical setting.

- Likelihood of exposure pathways and land uses actually occurring. A large part of the risk assessment is the estimation of cancer risks or hazard indices that are conditional on the existence of the exposure conditions analyzed; e.g., if a residential development is built on the site 10 years from now, the health risks associated with contaminants from the site would be X. It is important to provide the RPM or other risk manager with information related to the likelihood that the assumed conditions will occur to allow interpretation of a conditional risk estimate in the proper context. For example, if the probability that a residential development would be built on the site 10 or 50 years from now is very small, different risk management decisions might be made than if the probability is high. Present the information collected during scoping and for the exposure assessment that will help the RPM to identify the relative likelihood of occurrence of each exposure pathway and land-uses, at least qualitatively (e.g., institutional land-use controls, zoning, regional development plans).

- The chemicals not included in the quantitative risk estimate as a consequence of missing information on health effects or lack of quantitation in the chemical analysis may represent a significant source of uncertainty in the final risk estimates. If chemicals with known health effects were eliminated from the risk assessment on the basis of concentration or frequency of detection, one should now review and confirm whether or not any of the chemicals previously eliminated should actually be included. For substances detected at the site, but not included in the quantitative risk assessment because of data limitations, discuss possible consequences of the exclusion on the risk assessment.

A checklist of uncertainty factors related to the definition of the physical setting is described in the box below.

LIST PHYSICAL SETTING DEFINITION UNCERTAINTIES

- For chemicals not included in the quantitative risk assessment, describe briefly: -reason for exclusion (e.g., quality control), and -possible consequences of exclusion on risk assessment (e.g., because of widespread contamination, underestimate of risk).
- For the current land uses describe: -sources and quality of information, and. -qualitative confidence level.
- For the future land uses describe: -sources and quality of information, and -information related to the likelihood of occurrence.
- For each exposure pathway, describe why pathway was selected or not selected for evaluation (i.e., sample table format from Exhibit 6-8).
- For each combination of pathways, describe any qualifications regarding the selection of exposure pathways considered to contribute to exposure of the same individual or group of individuals over the same period of time.

Model applicability and assumptions. There is always some doubt as to how well an exposure model or its mathematical expression (e.g., ground-water transport model) approximates the true relationships between site-specific environmental conditions. Ideally, one would like to use a fully validated model that accounts for all the known complexities in the parameter interrelationships for each assessment. At present, however, only simple, partially validated models are available and commonly used. As a consequence, it is important to identify key model assumptions (e.g., linearity, homogeneity, steady-state conditions, equilibrium) and their potential impact on the risk estimates. In the absence of field data for model validation, one could perform a limited sensitivity analysis (i.e., vary assumptions about